

Application No.: 10/723,247
Office Action mailed: December 29, 2009
Response dated June 29, 2009

REMARKS

Claims 46, 49-53, 81, 186, 194-199, 217-220, 246, 272-273 and 280-299 are pending. No claim amendments have been made in this response thus the listing of claims filed on October 3, 2008 and entered by the Examiner, represent the pending claims.

A. Allowable Claims

The Examiner states that Claims 272-273 are allowed, and that Claim 281 would be allowable if written in independent format. The Examiner's allowance of these claims is acknowledged with appreciation.

However, there are apparently no rejections made against pending Claims 287 and 294, so their status is unclear.

B. Section 103 Rejections

The Applicant contends that both Section 103 rejections are improper. In the present Office Action, the Examiner has made two section 103 rejections. In both rejections the primary reference is U.S. Patent No. 5,279,814 (Wuelknitz et al.). Wuelknitz et al. teaches dental compositions. In addition, the Examiner relies on a secondary reference in each of the two rejections (U.S. Patent No. 6,780,844 (Reynolds) or U.S. Patent No. 6,503,483 (Shuch et al.)), each of which also teaches dental compositions

In the restriction requirement dated March 27, 2006, the Examiner required restriction between the pharmaceutical compositions of the presently rejected claims and claims directed to oral care compositions. In doing so, the Examiner took the position that the pharmaceutical compositions of the rejected claims are patentably distinct (*i.e.*, novel and not obvious) from oral care compositions, such as those taught by Wuelknitz et al., Reynolds and Shuch et al. (see the three paragraphs discussing inventions 3, 6, 7, 8 and 9 on pages 3-4 of the restriction requirement). Accordingly, Wuelknitz et al., Reynolds and Shuch et al. are not proper references against the rejected claims, and both rejections should be withdrawn for this reason alone.

Application No.: 10/723,247
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The Examiner has not responded substantively to this argument presented in Applicant's two prior responses. In the present Office Action, the Examiner does state: "It is of note that applicants' election filed 4/27/06 of Group 3 without traverse in response to the restriction requirement mailed 3/27/06." This is correct, and the Applicant did make the election without traverse because they agreed with the Examiner that the pharmaceutical compositions of the presently pending claims are patentably distinct (*i.e.*, novel and not obvious) from oral care compositions, thus the Applicant contends that the election without traverse only bolsters Applicant's argument.

1. Rejection of Claims 46, 49-53, 81, 186, 194-199, 217, 219-220, 246, 280, 282-286, 289-293, 295 and 297-299

The Examiner has rejected Claims 46, 49-53, 81, 186, 194-199, 217, 219-220, 246, 280, 282-286, 289-293, 295 and 297-299 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,279,814 (Wuelknitz et al.) in view of Jiang et al., *J. Agric. Food Chem.*, **48**:990-994 (2000) (Jiang) and U.S. Patent No. 6,780,844 (Reynolds).

Applicant respectfully traverses this rejection. Even assuming that Wuelknitz et al. and Reynolds are proper references, which Applicant contends they are not, the combined teachings of Wuelknitz et al., Jiang and Reynolds would not have made the rejected claims obvious.

Wuelknitz et al. teaches dental compositions comprising phosvitin. The phosvitin, in combination with fluoride, is used to protect the teeth against demineralization of the enamel. As correctly noted by the Examiner, the phosvitin used in the Wuelknitz et al. compositions is phosvitin as it is obtained from egg yolks without any dephosphorylation. Indeed, dephosphorylating phosvitin for use in the Wuelknitz et al. compositions would have been contrary to the teachings of Wuelknitz et al. that phosphorylation is necessary for the activity of phosvitin to protect teeth against demineralization of enamel. See column 1, lines 18-30 of Wuelknitz et al.

Application No.: 10/723,247

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Jiang teaches that dephosphorylated fragments of phosvitin can be used to solubilize calcium, remove calcium from insoluble phosphate precipitates and inhibit the formation of insoluble calcium phosphate. See section entitled "Formation of Soluble Complexes with Calcium", pages 993-994 of Jiang. However, the primary constituent of tooth enamel is hydroxyapatite (see Wuelknitz et al., column 1, lines 26-30), and hydroxyapatite has the formula $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$. Solubilizing calcium, removing it from insoluble calcium phosphate precipitates and inhibiting the formation of insoluble calcium phosphate would, therefore, be detrimental to tooth enamel and could result in its demineralization. Protecting against demineralization is the goal of Wuelknitz et al., so those skilled in the art would have not used the peptides of Jiang in the oral and dental compositions of Wuelknitz et al.

Reynolds teaches complexes of amorphous calcium phosphate (ACP) with certain phosphopeptides. See, *e.g.*, column 2, lines 51-55 of Reynolds. These complexes can be used in dental compositions along with other ingredients to prevent demineralization and dental caries. See column 3, lines 42-47 of Reynolds. However, like Wuelknitz et al., Reynolds also teaches that the phosphopeptides are fully phosphorylated. See, *e.g.*, column 2, lines 54-55, and column 2, line 56 through column 3, line 7. There is no teaching or suggestion in Reynolds that dephosphorylated peptides, like those taught by Jiang, can or should be used in the Reynolds dental compositions. Indeed, Reynolds teaches the opposite. See, *e.g.*, Examples 2 and 3 of Reynolds.

For all of the above reasons, the combined teachings of Wuelknitz et al., Jiang and Reynolds would not have made the rejected claims obvious, and thus withdrawal of this rejection is respectfully requested.

2. Rejection of Claims 218 and 296

The Examiner has rejected Claims 218 and 296 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,279,814 (Wuelknitz et al.) in view of Jiang et al., *J. Agric.*

Application No.: 10/723,247
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Food Chem., **48**:990-994 (2000) (Jiang) and further in view of U.S. Patent No. 6,503,483 (Shuch et al.).

Applicant again respectfully traverses this rejection for the reasons given in the previous two sections. Further, Shuch et al. teaches nothing about phosvitin or other phosphorylated proteins and peptides. Therefore, Shuch et al. does not make up for the deficiencies of Wuelknitz et al. and Jiang et al as described above.

For all of the above reasons, the combined teachings of Wuelknitz et al., Jiang and Shuch et al. would not have made the rejected claims obvious, and thus the Applicant respectfully requests withdrawal of this rejection.

CONCLUSION

Applicant believes that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,
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Date: June 29, 2009